



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,544	10/26/2001	Steve A. Herweck	ATA-333	2463
959	7590	09/29/2003	EXAMINER	
LAHIVE & COCKFIELD 28 STATE STREET BOSTON, MA 02109			WOO, JULIAN W	
ART UNIT		PAPER NUMBER		
3731		U		
DATE MAILED: 09/29/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/045,544	HERWECK ET AL.
	Examiner Julian W. Woo	Art Unit 3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 July 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-57 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-7, 10-15, 19-21, 23, 24, 26-36, 38, 39, 41-54, 56 and 57 is/are rejected.
- 7) Claim(s) 8, 9, 16-18, 22, 25, 37, 40 and 55 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> .	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 7-9 and 57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to base claim 7, "multiple organs," unpatentable parts of the human body, are claimed as structural parts of the invention. With respect to claim 57, lines 1 and 2, "the cartridge exchange tool" lacks antecedent basis.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-7, 13-15, 19-21, 23, 24, 26-28, 30-32, 35, 36, 38, 39, 41-46, 48-51, and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Buselmeier (3,826,257). Buselmeier discloses, in figures 1-5, a body fluid cartridge exchange platform (10) or access device, where the device includes, *inter alia*, a hollow tubular platform housing (15) with first and second ends (at 15b and 15c), an arcuate flow path or channel, and respectively first and second openings at the ends; tubular cartridge inserts (17) or cartridges insertable and removable through the first and second openings and be used

for drug delivery, each having a flow path, a channel, first and second channel ports, or lumen; first and second hollow leg members (16) with first and second ports and multiple lumens in fluid communication with the platform and with organs; and a locking mechanism (e.g., ties according to col. 5, line 63 to col. 6, line 2) for each of the tubular cartridge inserts; where each of the cartridge tubular inserts provides a flow path having a diameter that varies from a diameter relatively greater than an internal diameter of the first hollow leg member to substantially the same diameter as the internal diameter of the first hollow leg member (see element 17 in figures 4 and 5), and where the first and second legs penetrate the skin of a patient (see figures 1 and 2) or minimally invasively implanted in a patient.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 10, 33, 53, and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buselmeier. Buselmeier discloses the invention substantially as claimed, but does not disclose first and second legs, each having a diameter of less than 10mm; nor does Buselmeier disclose a cartridge insert tool. However, Buselmeier discloses, in col., 5, line 63 to col. 6, line 2, that the size of an implant, including its legs, can be of a "suitable size" in order to match the sizes of the lumen of the artery and vein selected. Thus, it would have been a matter of design choice to size each of the first and second legs at a diameter of less than 10mm. The choice would be dependent upon the sizes of the lumen of the artery and vein selected. It would also be obvious to one having ordinary skill in the art at the time the invention was made, to apply a common, surgical tool, such as a forceps, as a cartridge insert tool. Forceps would provide a convenient means to grip and manipulate a cartridge for insertion and removal through a hollow tubular platform housing.

7. Claims 11, 34, and 52 rejected under 35 U.S.C. 103(a) as being unpatentable over Buselmeier in view of Schulte (3,853,126). Buselmeier discloses the invention substantially as claimed, but does not disclose first and second legs each comprising a microporous cell penetrable cuff disposed at a sub-dermal end of the first and second hollow leg members when implanted in a patient. Schulte teaches, in col. 1, lines 55-62 and col. 4, lines 30-50, microporous cell penetrable cuffs (60, 61) disposed at a sub-dermal end of first and second hollow leg members implanted in a patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Schulte, to apply cuffs to the first and second hollow leg members.

Such cuffs on the legs would provide a bar to the penetration of organisms, which might be sources of infection.

8. Claims 12, 29, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buselmeier in view of Santerre et al. (5,798,115). Buselmeier discloses the invention substantially as claimed, but does not disclose a bioactive coating disposed on at least a portion of the flow path between the first and second hollow leg members and through the tubular cartridge insert. Santerre et al. teach bioactive coatings for various implants. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Santerre et al., to include bioactive coating disposed on at least a portion of the flow path of Buselmeier's device. Such a coating would reduce infections caused by the presence of access devices in a patient's body.

Allowable Subject Matter

9. Claims 8, 9, 16-18, 22, 25, 37, 40, and 55 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Claim 57 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

11. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination discloses a body fluid cartridge exchange platform or access device with, *inter alia*, a housing having first and

second openings, first and second hollow leg members extending from the housing, and cartridge inserts or cartridges, where an external communicating passageway is coupled to one of the openings, where a locking mechanism on a cartridge insert comprises a flexible tab, where at least one marking is disposed on at least one of the cartridge insert and the platform housing, where the first leg extends in a staggered and divergent manner from the second leg with respect to the housing, where a cartridge has at least one external passage in communication with the channel of the cartridge, and where the housing has a generally oval cross-section.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Shihata (3,998,222), Colone (4,822,341), and Akbik (6,086,553) teach devices with housings and legs.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached at (703) 308-2496.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703) 308-0858. The official FAX number is (703) 872-9302.



Julian W. Woo
Primary Examiner

September 24, 2003